

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1101.21
True Name	Bovine Rhinotracheitis Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Bovi-Shield IBR - No distributor specified
Date of Compilation Summary	August 16, 2022

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

190 1101.21 Page 1 of 16

Study Type	Efficacy
Pertaining to	Herpesvirus, bovine (IBR)
Study Purpose	Demonstrate efficacy against respiratory disease caused by
	infectious bovine rhinotracheitis
Product Administration	
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	01/08/2001

190 1101.21 Page 2 of 16

Study Type	Efficacy
Pertaining to	Infectious bovine rhinothracheitis (IBR) virus
Study Purpose	Demonstrate a duration of immunity of at least 280 days against
-	respiratory disease caused by IBR virus
Product Administration	One dose administered subcutaneously
Study Animals	20 vaccinated and 10 control calves, four to five months of age,
	seronegative to IBR
Challenge Description	IBR virus administered 280 days post-vaccination
Interval observed after	Animals were observed daily for 14 days following challenge
challenge	
Results	IBR disease was the efficacy variable. IBR disease was defined as whether an animal ever exhibited one of the following clinical signs: depression, mucopurulent nasal discharge, and/or increased respiratory effort and sounds. IBR disease: Controls: 10/10 (100%) Vaccinates: 0/20 (0%) See individual data attached.
USDA Approval Date	March 19, 2010

190 1101.21 Page 3 of 16

IBR Disease by Treatment, Day and Animal

Controls

A *1									Day								
Animal	278	279	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294
39	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No						
42	No	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No						
43	No	Yes	Yes	Yes	Yes	No	No	No	No	No							
54	No	Yes	No	No	No												
56	No	Yes	No	No													
61	No	Yes															
62	No	Yes	Yes	No													
63	No	Yes	Yes	Yes	Yes	No	No	No	No	No							
65	No	Yes	No	No	No												
68	No	Yes	Yes	Yes	No	No	No	No	No	No							

Vaccinates

A 1									Day								
Animal	278	279	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294
37	No																
41	No																
44	No																
46	No																
47	No																
48	No																
49	No																
50	No																
51	No																
52	No																
53	No																
55	No																
57	No																
58	No																
59	No																
60	No																
64	No																
67	No																
71	No																
72	No																

190 1101.21 Page 4 of 16

Study Type	Efficacy
Pertaining to	Herpesvirus, bovine [Infectious Bovine Rhinotracheitis (IBR) Virus]
Study Purpose	Demonstrate efficacy against respiratory disease caused by IBR
Product Administration	One dose administered intramuscularly (IM) or subcutaneously (SC)
Study Animals	20 IM vaccinates, 20 SC vaccinates, and 10 control calves, 6–8 months of age and seronegative to IBR (serum neutralizing antibody titer < 1:2). The study was conducted per 9 CFR 113.310.
Challenge Description	IBR virus administered on day 35
Interval observed after	Animals were observed daily for 14 days
challenge	
Results	Animals were considered to have IBR disease if a clinical sign was observed/detected on at least one day post-challenge to include depression, nasal discharge, rectal temperature, or increased respiratory effort.
	Number of animals affected (IBR disease):
	Controls: 10/10 (100%)
	IM vaccinates: 4/20 (20%)
	SC vaccinates: 2/20 (10%)
USDA Approval Date	01/23/2008

190 1101.21 Page 5 of 16

IBR Disease: Depression

Treatment								St	udy D	ay						
Group	Animal Id	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49
1	2119	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2123	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0
	2145	0	0	0	0	0	1	1	1	1	0	1	1	0	0	0
<u>s</u>	2148	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0
[tro]	2153	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Controls	2161	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0
	2171	0	0	0	0	0	1	0	1	1	1	1	0	0	0	0
	2178	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0
	2197	0	0	0	0	0	0	1	1	1	1	1	1	0	1	0
	2200	0	0	0	0	0	0	1	1	1	1	1	1	0	0	0
	2122 2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2131	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2140	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2150	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2151	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	2155	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IM Vaccinates	2163	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
cin	2164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
/ac	2168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	2174	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2181	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2185	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2188	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2189	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2198	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2124 2125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2123	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2130	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2132	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SO	2133	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ates	2139	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
cin	2147	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
/ac	2149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SC Vaccinat	2156	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Š	2162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2169	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2172	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2175	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2177	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2193	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

^{0 =} Normal. Alert, active, stands, moves and responds to stimuli quickly and steadily, shows continuous interest in surroundings.

190 1101.21 Page 6 of 16

^{1 =} Mild. Tends to lie down frequently, lethargic and somnolent, stands, moves and responds to stimuli reluctantly and unsteadily, holds head low, staggers, shows little interest in surroundings.

^{2 =} Severe. Recumbent or shows little or no response to stimuli or stands/moves with difficulty.

IBR Disease: Nasal Discharge

Treatment								St	udy D	ay						
Group	Animal Id	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49
*	2119	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
	2123	0	0	0	0	0	1	0	0	0	1	0	1	1	0	0
	2145	0	0	0	1	1	1	1	1	1	1	0	1	0	1	0
α	2148	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0
trol	2153	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
Controls	2161	0	0	0	0	0	1	1	1	1	1	1	0	1	1	0
0	2171	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
	2178	0	0	0	0	1	1	0	0	0	1	1	1	0	0	0
	2197	0	0	0	0	0	1	0	1	1	1	1	1	1	0	1
	2200	0	0	0	0	0	0	1	1	1	1	1	0	1	0	0
	2122	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2127	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2131	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2140	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2150	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2151	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
es	2155	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SC Vaccinates	2163	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
cci	2164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Va	2168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SC	2174	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
•	2176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2181	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2185	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2188	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2189 2198	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2198	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2124	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2123	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2128	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2130	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	2132	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
, m	2133	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ates	2139	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sing	2147	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IM Vaccinat	2149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
A V	2156	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0
	2162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2169	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2172	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	2175	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2177	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2193	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

^{0 =} No discharge/small amount of discharge (approx. 1 mL or less) of clear, mucoid or whitish discharge.

190 1101.21 Page 7 of 16

^{1 =} Mild. Notable amount (approx. 2–3 mL or more) of clear mucoid discharge streaked with mucopurulent discharge running down the nostrils.

^{2 =} Severe. Notable amount (approx. 2–3 mL or more) of mucopurulent discharge running down the nostrils.

IBR Disease: Respiratory Effort

Treatment								St	udy D	av						
Group	Animal Id	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49
1	2119	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2123	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2145	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<u>s</u>	2148	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
tro	2153	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Controls	2161	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	2171	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
	2178	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2197	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2200	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2122 2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2131	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2140	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2150	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2151	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
70	2155	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SC Vaccinates	2163	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
cin	2164	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
/ac	2168	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
C	2174	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
S	2176	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2181	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2183	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2185	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2188	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2189	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2198	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2199	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2124 2125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2123	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2129	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2130	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2132	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
100	2133	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ates	2139	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
cin	2147	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
/ac	2149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
IM Vaccinat	2156	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2162	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2166	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2167	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2169	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2172	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2175	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2177	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2193	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

^{0 =} Normal. Respirations are shallow and mostly thoracic (difficult to see at a distance of approximately 10 feet).

190 1101.21 Page 8 of 16

^{1 =} Mild. Respirations are rapid, labored and mostly abdominal.

^{2 =} Severe. Respirations are very labored or animal grunts during breathing.

Rectal Temperatures (°C)

Treatment								St	udy D	ay						
Group	Animal Id	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49
	2119	39.1	38.9	38.9	40.9	40.4	40.4	40.5	39.9	39.5	39	38.7	38.5	38.7	38.7	38.7
	2123	39.2	39.1	40.4	41.6	41.5	41.4	40.4	40.5	40.7	40.6	39.9	39	38.9	38.8	38.6
	2145	39.4	39	39.2	41.7	41.3	41.1	40.6	39.7	40	40	38.9	38.8	39.2	39.2	39
<u>s</u>	2148	39.1	39.3	39.3	40.8	41.3	40.4	40.4	40	39.5	39.1	39	39.1	38.7	38.7	38.6
Controls	2153	39.4	39.2	39.3	39.9	40.7	40.4	40	39	39.6	39.2	39.2	38.9	39.3	39.3	39.1
yon	2161	39.2	39.6	41	42.3	41.7	41.5	40.9	40.4	40.1	39.9	39.3	39.3	38.9	39	38.7
	2171	39.3	39.2	39.3	41.8	40.7	40.9	40.7	40.6	40.6	40.6	39.6	39.3	38.8	39.2	38.6
	2178	39.2	39.2	38.8	41.2	41.7	41.2	41.1	40.7	40.1	39.4	39.2	39.1	38.9	39.1	39.1
	2197	39.1	39	39.4	41.6	41.4	40.4	40.4	40.5	39.6	39.7	39	39.1	38.6	38.9	38.8
	2200	39.5	39.3	39.3	41.1	40.6	40.9	40.3	40.2	39.7	39.8	38.9	39.1	38.8	38.9	39.1
	2122	39.3	39.1	39.3	39.2	39.5	39	39.1	39	39	38.9	39.2	38.7	39.1	39.1	39.2
	2126	39	38.8	38.9	38.9	38.7	38.8	39	38.6	38.9	38.9	38.8	38.9	38.6	38.7	38.7
	2127	39.4	39.3	39	39.3	39.1	39.1	39.6	39.1	39.5	39.2	39.2	39.3	39.4	38.9	38.9
	2131	39.1	39	38.8	39.2	39	38.8	38.7	39.7	39.4	38.7	38.8	38.7	39.1	38.8	39.1
	2140	39.1	38.9	39	38.6	38.7	38.8	38.8	38.7	38.8	38.7	38.6	38.7	38.7	39.1	38.8
	2150	38.9	39	38.9	38.8	39.1	39	38.7	38.6	38.8	38.9	38.8	38.7	38.9	38.9	38.9
	2151	39.3	39.2	39	39	38.9	38.7	38.9	38.9	38.8	38.8	38.7	38.8	38.8	38.9	38.5
es	2155	39.3	39.2	38.7	39	39.2	38.8	39	38.8	38.9	39.1	39	39.1	39	38.8	38.9
SC Vaccinates	2163	39.2	39	38.9	38.9	38.9	39	39.3	38.7	38.6	38.8	38.9	39	38.7	39.1	39
icci	2164	39.2	39.3	39.3	39	39.5	39.4	39	39.3	39.1	39.2	39	39.3	38.8	38.7	38.9
\sigma	2168	38.7	38.9	38.7	39	39.1	39	38.7	38.9	39	38.8	38.8	38.7	39	38.7	39.2
SC	2174	39	38.9	38.9	40.4	40.5	40.3	38.9	38.8	38.7	38.9	38.9	39	38.8	38.6	38.8
	2176	39	38.8	39.1	39.3	38.8	39.1	38.8	38.8	39.1	38.9	39.1	38.8	38.7	38.6	39
	2181	38.9	39.2	38.7	38.8	39.2	39.4	39.2	39.3	38.9	39.1	38.8	38.7	39	38.8	39.1
	2183	38.9	38.9 39.6	38.8	39	39.1	39 39.9	38.8 39.1	38.7	38.8	38.8	39 39.2	39.1 39.1	38.5	39	39.1
	2185 2188	39.2 39.4	39.5	39.5 39.6	40.5 39.4	40.1 39.1	39.4	39.1	39.3	39.1 39.2	39.1 39.4	39.4	39.1	39 39.3	38.8 39.1	39.3 39.2
	2189	38.8	38.8	39.0	38.6	39.1	38.7	38.7	39.4 38.8	39.2	38.9	39.4	39.1	38.9	39.1	38.7
	2198	39.3	39.2	38.9	39.1	38.8	39	39.1	39	38.8	38.9	38.9	39.1	38.8	38.8	38.7
	2199	39.1	39.2	39	38.9	39.2	38.9	38.9	39.1	39.3	39	39	39	38.8	38.8	38.8
	2121	38.9	39.1	38.9	38.7	39.2	39	38.8	38.9	39.2	38.7	39.1	38	38.7	38.9	38.9
	2124	39	38.9	39.1	39.2	39	39	39.1	38.9	39.1	38.8	39.2	38.9	39	38.7	38.9
	2125	39	38.8	38.8	38.8	38.9	38.8	38.8	38.9	38.9	38.9	39.1	39.1	38.9	39	39.1
	2128	39.2	39	39.1	38.9	38.9	39.1	38.7	39.2	39.1	38.9	38.9	38.9	38.9	38.9	38.8
	2129	39	39.2	39.2	39.3	39.3	39.2	38.9	39.4	39.1	39.1	39.4	38.7	38.9	38.8	39.1
	2130	39	39.2	39	39.3	38.9	38.9	38.9	39.1	39.2	39	39	39.1	38.7	38.6	38.8
	2132	39.6	39.9	39.4	39.2	39.5	39.4	39.2	39	39.2	39	39.3	39.1	39.2	39	39.1
70	2133	38.9	38.8	38.8	38.9	38.8	38.8	38.9	38.7	38.8	38.6	39.1	38.8	38.8	38.6	38.7
ates	2139	39	39.2				38.8		39.1							38.8
IM Vaccina	2147	39	39	38.9	38.8	39	38.9	38.8		38.7	38.7	38.6	38.8	39.2	38.7	38.8
/acı	2149	39.2	39.2	38.9	39.1	39	38.8	38.8		38.7	38.7	39.2	38.7	38.7	38.7	38.9
1.7	2156	39	38.9	38.9	39.1	39.2		39.2		38.6	38.8		38.7	38.9	38.8	39.1
	2162	38.9	39.3	39.3	38.9	39.2	39.4	38.9	39	39	38.9		38.9	38.8	38.7	39.1
	2166	39.2	39.1	38.9	39.3	39.1	39.1	38.8	39	38.9	39.2	39.3	39.1	38.9	38.9	38.8
	2167	38.9	38.6	38.7	38.7	38.7	38.7	38.9	38.6	38.7	38.8		38.8	38.7	38.9	38.7
	2169	39.3	39.1	38.9	39	39	39.3	38.9	39	39.2	38.9	39.1	39.1	38.8	39	39
	2172	39.9	39	38.8	39.2	38.8	38.9	39.1	39.1	38.9	38.9	38.9	39	38.9	38.8	38.6
	2175	39.1	38.8	38.6	38.6	38.9	39	38.7	38.7	38.8	38.6	38.9	39	38.7	38.9	38.6
	2177	39.1	39.5	39.3	39.3	39	39	38.9		38.7	39	39.6	38.9	39.1	38.9	39
	2193	39	39.3	39	39.1	39.3	38.9	38.8		39.1	39	38.8				39
	=-/-							- 5.0	1		′	- 5.0				

190 1101.21 Page 9 of 16

IBR Serum Neutralization

			Study	/ Day	
Treatment Group	Animal Id	0	27	34	49
	2119	<2	<2	<2	38
	2123	<2	<2	<2	23
	2145	<2	<2	<2	76
<u> </u>	2148	<2	<2	<2	54
lo.	2153	<2	<2	<2	38
Controls	2161	<2	<2	<2	54
ا ٽ	2171	<2	<2	<2	76
-	2178	<2	<2	<2	27
-	2197	<2	<2	<2	76
	2200	<2	<2	<2	76
	2122	<2	11	16	431
-	2126	<2	32	23	215
-	2127	<2	16	16	215
	2131	<2	29	27	128
	2140	<2	27	23	152
	2150	<2	19	19	181
	2151	<2	23	23	304
-	2155	<2	38	45	45
SC Vaccinates	2163	<2	14	16	215
ji.	2164	<2	19	19	152
acc a	2168	<2	36	23	181
>	2174	<2	6	4	362
S -	2176	<2	13	19	609
	2181	<2	23	23	304
	2183	<2	9	10	304
	2185	<2	10	5	512
	2188	<2	13	11	362
-	2189	<2	13	13	215
-	2198	<2	32	32	181
-	2199	<2	18	27	362
	2121	<2	23	27	128
-	2124	<2	16	16	256
	2125	<2	16	19	45
	2128	<2	19	19	362
	2129	<2	16	16	54
	2130	<2	27	23	256
	2132	<2	13	16	304
ν _ο	2133	<2	38	45	304
IM Vaccinates	2139	<2	32	45	76
2 jing	2147	<2	13	16	256
ac.	2149	<2	45	38	181
1	2156	<2	13	13	91
	2162	<2	13	10	609
	2166	<2	11	13	431
	2167	<2	27	23	108
	2169	<2	11	13	152
	2172	<2	19	23	152
	2175	<2	13	16	152
	2177	<2	6	6	256
	2193	<2	45	45	181

Titers are expressed as the greatest neutralizing dilution.

190 1101.21 Page 10 of 16

Study Type	Efficacy
Pertaining to	Herpesvirus, bovine [Infectious Bovine Rhinotracheitis (IBR)]
Study Purpose	Demonstrate efficacy against respiratory disease caused by IBR
Product Administration	
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	01/08/2001

190 1101.21 Page 11 of 16

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in calves nursing pregnant cows
Product Administration	
Study Animals	Bovine
Challenge Description	NA
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	08/06/2002

190 1101.21 Page 12 of 16

Study Type	Safety
Pertaining to	Herpes Virus, Bovine [Infectious Bovine Rhinotracheitis (IBR)
	virus]
Study Purpose	Demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine
Challenge Description	NA
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	05/13/1998

190 1101.21 Page 13 of 16

Study Type	Safety
Pertaining to	Herpes Virus, Bovine [Infectious Bovine Rhinotracheitis (IBR)
	virus]
Study Purpose	Demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine
Challenge Description	NA
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	08/06/2002

190 1101.21 Page 14 of 16

Study Type	Safety
Pertaining to	Herpes Virus, Bovine [Infectious Bovine Rhinotracheitis (IBR)
	virus]
Study Purpose	Demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine
Challenge Description	NA
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	08/06/2002

190 1101.21 Page 15 of 16

Study Type	Safety
Pertaining to	Herpes Virus, Bovine [Infectious Bovine Rhinotracheitis (IBR)
	virus]
Study Purpose	Demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine
Challenge Description	NA
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	05/13/1998

190 1101.21 Page 16 of 16